

CLAIMS

What is claimed is:

1. An isolated avian hepatitis E virus having a nucleotide sequence set forth in SEQ
5 ID NO:1 or its complementary strand.
2. The avian hepatitis E virus according to Claim 1, wherein said virus has no more
than about 80% nucleotide sequence identity to an Australian big liver and spleen disease
virus.
3. An isolated polynucleotide comprising a member selected from the group
10 consisting of:
 - (a) a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand;
 - (b) a polynucleotide which hybridizes to and which is at least 95%
complementary to the nucleotide sequence set forth in SEQ ID NO:1; and
 - (c) an immunogenic fragment selected from the group consisting of a nucleotide
15 sequence in the partial helicase gene of ORF1 set forth in SEQ ID NO:3, a nucleotide
sequence in the RdRp gene set forth in SEQ ID NO:5, a nucleotide sequence in the ORF2
gene set forth in SEQ ID NO:7, a nucleotide sequence in the ORF3 gene set forth in SEQ
ID NO:9 and their complementary strands.
4. A purified, immunogenic protein encoded by the isolated polynucleotide
20 according to Claim 3.
5. The protein according to Claim 4, wherein the protein comprises an ORF2 capsid
protein or an ORF3 protein.
6. An immunogenic composition comprising a nontoxic, physiologically acceptable
carrier and an isolated avian hepatitis E virus having a nucleotide sequence set forth in
25 SEQ ID NO:1, its complementary strand, an isolated polynucleotide according to Claim 3
or an antigenic protein encoded by the isolated polynucleotide.
7. A diagnostic reagent for detecting an avian hepatitis E viral infection or
diagnosing hepatitis-splenomegaly syndrome in an avian or mammalian species
comprising an antibody raised or produced against the immunogenic composition
30 according to Claim 6.

8. A vaccine that protects an avian or mammalian species from viral infection or hepatitis-splenomegaly syndrome caused by an avian or mammalian hepatitis E virus comprising a nontoxic, physiologically acceptable carrier and a member selected from the group consisting of:

5 (a) a modified live avian hepatitis E virus, having a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand;

(b) an inactivated avian hepatitis E virus, having a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand;

10 (c) an attenuated avian hepatitis E virus, having a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand;

(d) an antigenic subunit of avian hepatitis E virus, having a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand; and

15 (e) a purified, immunogenic protein encoded by an isolated polynucleotide comprising a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand; a polynucleotide which hybridizes to and which is at least 95% complementary to the nucleotide sequence set forth in SEQ ID NO:1; or an immunogenic fragment selected from the group consisting of a nucleotide sequence in the partial helicase gene of ORF1 set forth in SEQ ID NO:3, a nucleotide sequence in the RdRp gene set forth in SEQ ID NO:5, a nucleotide sequence in the ORF2 gene set forth in SEQ ID NO:7, a nucleotide
20 sequence in the ORF3 gene set forth in SEQ ID NO:9 and their complementary strands.

9. The vaccine according to Claim 8, wherein said virus is inactivated or attenuated by serial passage of the virus through embryonated chicken eggs.

10. The vaccine according to Claim 8, wherein said vaccine further contains an adjuvant.

25 11. A method of protecting an avian or mammalian species from viral infection or hepatitis-splenomegaly syndrome caused by the avian or mammalian hepatitis E virus comprising administering an immunologically effective amount of the vaccine according to Claim 8 to an avian or mammalian species in need of protection against said infection or syndrome.

30 12. The method according to Claim 11, wherein the vaccine is administered to a chicken, a pig or a human.

13. The method according to Claim 11, wherein the vaccine is administered orally, intrabuccally, intranasally, transdermally or parenterally.

14. A method for propagating, inactivating or attenuating a hepatitis E virus comprising inoculating an embryonated chicken egg with a live, pathogenic hepatitis E virus and recovering a live, pathogenic hepatitis E virus or serially passing the pathogenic virus through additional embryonated chicken eggs until said virus is rendered inactivated or attenuated.

15. The method according to Claim 14, wherein the live, pathogenic hepatitis E virus is injected intravenously into the embryonated chicken egg.

16. The method according to Claim 14, wherein said hepatitis E virus is an avian hepatitis E virus having a nucleotide sequence set forth in SEQ ID NO:1 or its complementary strand.

17. A method for detecting an avian hepatitis E viral infection or diagnosing hepatitis-splenomegaly syndrome in an avian or mammalian species comprising contacting a biological sample of the avian or mammalian species with the diagnostic reagent according to Claim 7 and detecting or observing the presence of an antigen-antibody complex.

18. The method according to Claim 17, wherein the biological sample is taken from a chicken, a pig or a human.

19. A method for detecting an avian hepatitis E viral nucleic acid sequence in an avian or mammalian species comprising isolating nucleic acid from the avian or mammalian species, hybridizing the nucleic acid and determining the presence or absence of a hybridized probe complex.

20. The method according to Claim 19, wherein the nucleic acid is hybridized with a radio-labeled or a non-radiolabeled nucleic acid probe derived from the nucleotide sequence set forth in SEQ ID NO:1 or hybridized with a pair of oligonucleotide primers derived from the nucleotide sequence set forth in SEQ ID NO:1 and further amplified in a polymerase chain reaction.